Remarks

In response to the Office Action mailed June 6, 2001, Applicants respectfully request reconsideration. To further prosecution of this application, Applicants submit the following remarks. The claims as presented are believed to be in allowable condition.

Claims 1-21 are currently active in the application. Applicants have amended independent claims 1, 8, 14, and 20. Claims 1 and 8 were amended to clarify the requirement that the second valving means (Claim 1) or control valve (Claim 8) partially restricts fluid flow. This amendment finds support on page 5, lines 7-14; page 8, line 31 through page 9, lines 1-15; and page 13, line 18 through page 14, line 7. Claim 14 was amended to clarify the requirement that the membrane of the pressure-conduction chamber has a structure for creating an instability in the filled-chamber position and promoting a collapse of the membrane from the filled-chamber position to the empty-chamber position. Claim 20 was amended to clarify the requirement that the membrane of the pressure-conduction chamber has a structure which may be actuated to increase instability and reduce resistance of the membrane to initial movement from the empty-chamber position to the filled-chamber position. These amendments find support on page 10, lines 3-31 through page 11, lines 1-22. No new matter has been added.

Claims 1, 8, and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Abbott et al. (U.S. Patent 5,588,816). Claims 2-7, 9-19, and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Abbott et al. and/or Pastrone et al. in that the limitations in these claims are obvious design alternatives.

The present invention as set forth in claims 1-12 provides a structure for making more continuous the flow rate to the patient receiving IV fluid. The cited references do not address this issue and do not provide a valve that permits the smoothing out of the flow rate in the same manner as the present invention.

The present invention as set forth in claims 14-21 provides a membrane that is less likely to remain stuck in either the maximum-volume position (claim 14) or the minimum-volume position (claim 21). The greater the tendency of the membrane to remain in one position, the more difficult measuring and controlling the flow rate becomes. The cited references also do not address this issue and do not provide any teaching to provide instability to the membrane in either the maximum-volume position or the minimum-volume position.

Rejections under 35 U.S.C. §102(b)

Claims 1 and 8

The Abbott et al. patent shows a cassette for a cardioplegia delivery system including six valves (84, 86, 88, 90, 92, and 94 in Fig. 2) for occluding (i.e., closing) the flow paths for blood or crystalloid through the cassette for delivery to a line 28 (Fig. 1; Col. 5, lines 19-50). Through opening and closing, the valves alternately control the passage of blood or crystalloid, which is stored in pump chambers 74 and 76, to outlet path 82 (Fig. 2). The cassette shown in Fig. 2 of Abbott et al. does not include a second valving means downstream from a first valving means, wherein a charge of pressurized fluid from a valving chamber is urged through the second valving means, which partially restricts the flow to the patient as required by claim 1. Here, the second valving means controls the flow rate of the fluid. The valves taught by Abbott et al. are in either an open state, thus allowing a full flow of fluid through the outlet path, or in a closed state, thus allowing no flow of fluid through the outlet path (Col. 6, lines 29-49 and Col. 7, lines 14-44). None of the valves taught by Abbott et al. allow the flow of fluid while partially restricting the flow to the patient. Because the Abbott et al. patent does not teach a valve for partially restricting the flow rate of a fluid as taught in claim 1, it fails to disclose all of the essential features of the claimed invention. Thus, claim 1 is in condition for allowance.

Furthermore, the Abbott et al. patent does not teach or suggest a system wherein a charge of pressurized fluid passes through a second valve that partially restricts flow to the patient and thereby permits a more even flow rate to the patient. Accordingly, the rejection of claim 1 under 35 U.S.C. §102(b) should be withdrawn.

Claim 8, (which is directed towards a control valve for restricting the flow rate of a fluid), is directed to similar novel features as amended claim 1, and is allowable for reasons similar to those set forth above for claim 1.

Claim 20

The Abbott et al. patent fails to disclose any teaching anticipating claim 20. The reference shows a cassette (Fig. 4) in which bladder pumping chambers (74, 76) are filled and emptied through the advancement and retraction of motors (95, 96) against hub 130 which is surrounded by radially extending, pivotally mounted petals 132 (Col. 5, lines 62-67 through Col. 6, lines 1-20). The reference fails to teach a membrane which may be actuated to increase instability and reduce resistance of the membrane to initial movement from the empty-chamber position to the filled-chamber position after a gas pressure is applied to the membrane. Thus, Abbott et al. fails to disclose all of the essential features of the claimed invention, and claim 20 is in condition for allowance. Accordingly, the rejection of claim 20 under 35 U.S.C. §102(b) should be withdrawn.

Rejections under 35 U.S.C. §103(a)

The Pastrone et al. patent shows a cassette (Fig. 2C) including a pumping chamber 52 having a bulb-like recess 71. A mechanical reciprocating plunger mechanism 74 selectively works an elastomeric member 73 back-and-forth into the bulb-like recess 71 (Col. 2, lines 46-48 and Col. 3, lines 22-30). Therefore, neither the Pastrone et al. patent nor the Abbott et al. patent

discussed above with respect to claim 20, alone or in combination, teaches or suggests a membrane structure for promoting a collapse of the membrane from the filled-chamber position to the empty-chamber position, as disclosed in claim 14. These references show mechanical means for urging a membrane back and forth. Providing a membrane with a structure to promote its collapse is not an obvious design alternative. The structure of the membrane is patentably significant in that this structure reduces the tendency of the membrane to remain in the filled-chamber position when the pressure-conduction chamber is full. Thus, this structure makes it easier to collapse the membrane than if the structure was not present. See Page 11, lines 14-22 of the Specification.

Since neither reference teaches or suggests such a structure for promoting the collapse of a membrane from a filled-chamber position to an empty-chamber position, claim 14 is patentably distinguishable over these references alone or in combination. Accordingly, the rejection of claim 14 under 35 U.S.C. §103(a) should be withdrawn.

Claims 2-7 depend from amended claim 1 with each claim adding at least one additional limitation. For example, claim 3 requires the valving chamber to be provided with a membrane that allows the chamber to expand and accept a charge of fluid. The cited references do not suggest that the membrane of the valving chamber may be used in such a manner. Thus, claims 2-7 are allowable for the reasons stated above with respect to claim 1 as well as the additional limitations set forth therein. Therefore, the rejections of claims 2-7 under 35 U.S.C. §103(a) should also be withdrawn.

Claims 9-13 depend from claim 8 with each claim adding at least one additional limitation. For example, claim 13 requires the structure of the membrane to cause the collapse of the membrane to occur in the region of the second mouth before collapsing near the first mouth.

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The cited references do not suggest such a structure. Thus, claims 9-13 are allowable for the reasons stated above with respect to claim 8 as well as for the additional limitations set forth herein. Therefore, the rejections of claims 9-13 under 35 U.S.C. §103(a) should also be withdrawn.

Claims 15-19 depend from claim 14 with each claim adding at least one additional limitation. For example, claim 16 requires that the pressure-conduction chamber define an obstructed fluid passageway from the first to the second mouth even when the membrane is in the empty-chamber position. No such structure is disclosed in the cited references. Thus, claims 15-19 are allowable for the reasons stated above with respect to claim 14 as well as for the additional limitations set forth therein. Therefore, the rejections of claims 15-19 under 35 U.S.C. §103(a) should also be withdrawn.

Claim 21 depends from amended claim 20, adding a tab on the exterior of the membrane that may be actuated to lift a portion of the membrane from the rigid housing. The cited references teach no such structure. Therefore, the rejection of claim 21 under 35 U.S.C. §103(a) should also be withdrawn.

In view of the foregoing remarks, this application is now in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is invited to call the Applicants' attorney at the number listed below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

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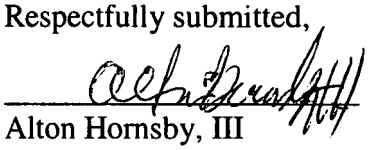
Respectfully submitted,



Alton Hornsby, III
Registration No. 47,299
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110-1618
(617) 443-9292

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 1, 8, 14, and 20 have been amended as follows:

1. (Amended) A cassette for use in a system for controlling the flow of fluid downstream from a source to a patient, the cassette comprising:

first valving means located downstream from the source, the first valving means comprising a valving chamber; and

second valving means located downstream from the first valving means in line with the valving chamber and the patient;

wherein the first valving means, while sealed closed preventing fluid communication from the source, is adapted to urge a charge of pressurized fluid downstream through the second valving means to the patient, the second valving means [restricts] partially restricting the flow to the patient.

8. (Amended) A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:

a membrane-based valve comprising:

a rigid housing, having a first mouth, a first passage, a second mouth, and a second passage; and

a compliant membrane; and

a control valve located between the membrane-based valve and the patient;

the housing and the membrane coupled, defining a valving chamber, the first passage entering the valving chamber at the first mouth located such that flow of fluid via the first passage into the chamber may be prevented when the membrane is forced against the first mouth, the second passage exiting the valving chamber at the second mouth, so that a charge of pressurized fluid may be urged by the compliant membrane to continue flow from the valving chamber into and through the second passage via the second mouth toward the patient and may be provided to the patient when both the membrane is forced against the first mouth and the control valve partially restricts fluid flow.

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14. (Amended) A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:

a rigid housing; and

a membrane disposed adjacent the rigid housing;

the rigid housing and the membrane defining a pressure-conduction chamber;

wherein a pressure-conduction chamber portion of the rigid housing is generally dome-shaped, the membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is substantially at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the pressure-conduction chamber portion of the rigid housing, the membrane having a structure for creating an instability in the filled chamber position and promoting a collapse of the membrane from the filled-chamber position to the empty-chamber position.

20. (Amended) A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:

a rigid housing; and

a membrane disposed adjacent the rigid housing;

the rigid housing and the membrane defining a pressure-conduction chamber;

wherein a pressure-conduction chamber portion of the rigid housing is generally dome-shaped, the membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is substantially at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the pressure-conduction chamber portion of the rigid housing, the membrane having a structure which may be actuated to increase instability and reduce resistance of the membrane to initial movement from the empty-chamber position to the filled-chamber position.